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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,097	09/12/2003	Andrew Vaillant	029849-0204	6581

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EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,097	VAILLANT ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) 3-13 and 33-38 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2 and 14-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5-8-06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: SEQ Compliance Notice

DETAILED ACTION

This Office action is in response to the communications filed 10-5-06.

Claims 1-38 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed 10-5-06 is insufficient to overcome the rejection of claims 1, 2 and 14-32 based upon 35 U.S.C. 112, first paragraph as set forth in the last Office action and for the reasons set forth below.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Please provide SEQ ID Nos. for the oligonucleotide sequence disclosed throughout the specification (see e.g., Table 1 and the figures).** See the accompanying Notice to Comply.

Election/Restrictions

This application contains claims 3-13 and 33-38 drawn to an invention nonelected with traverse in the election filed 3-1-06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 1, 2 and 14-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 4-5-06.

Applicant's arguments and declaration filed 10-5-06 have been fully considered but they are not fully persuasive. Applicant argues that adequate description has been provided for the broad genus of compounds claimed. Applicant argues that the three species of oligonucleotides disclosed, which were found to provide treatment and prophylactic effects in an appropriate animal model, indeed provide adequate description of the genus comprising any oligonucleotide at least 29 nucleotides in length which provides anti-viral activity by a non-sequence complementary mode of action, and which is non-sequence complementary (*e.g.*, to a viral gene).

The claims are drawn to methods for the prophylaxis or treatment of HSV-1, HSV-2 or CMV infection in a subject comprising the administration of any oligonucleotide at least 29 nucleotides in length which provides anti-viral activity by a non-sequence complementary mode of action, and which is non-sequence complementary. The specification and claims do not adequately describe the distinguishing features or attributes concisely shared by the members of the genus comprising oligonucleotides with non-sequence complementary modes of action and comprising random sequences, whereby prevention and treatment of HSV-1, HSV-2 or CMV is obtained in an organism.

The declaration filed 10-5-06 describes two oligonucleotides (REP 2006 and 2031), found to prevent HSV-2 transmission in a mouse model, as well as three oligonucleotides (REP 2006, 2031 and 2107) found to reduce CMV liver titers upon intraperitoneal administration. The specification teaches rather large differences in the abilities of various randomers to inhibit different viral infections, and each randomer must be tested empirically. The disclosure of three effective oligonucleotides found to reduce or prevent viral infectivity in some strains of virus, and the disclosure of various means to assay oligonucleotide candidates for effectiveness in reducing viral growth or infectivity, do not provide adequate description of the very large genus claimed. One of skill in the art would reasonably conclude that Applicant was not in possession of the very broad genus of compositions claimed at the time of filing.

The disclosure does not clarify the common attributes encompassed by this very broad genus. Concise structural features that would distinguish structures within the

broadly claimed genus of sequences are missing from the disclosure, and without empirically testing each candidate oligomer, it is unclear which of these species would provide for the functions claimed, the ability to prevent or inhibit HSV-1, HSV-2 and/or CMV infections in a subject.

For these reasons, the very broad large genus claimed was not adequately described at the time of filing by Applicant.

Claims 1, 2 and 14-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set forth in the Office action mailed 4-5-06.

Applicant's arguments and declaration filed 10-5-06 have been fully considered but they are not fully persuasive. Applicant argues that the full scope of the claims is enabled because the instant disclosure, at examples 2 and figure 15, disclose various oligonucleotides with different lengths used to identify their efficacy as potential anti-HSV-2 molecules. In addition, according to Applicant, in vivo efficacy has been shown for three oligonucleotides - two oligonucleotides (REP 2006 and 2031) were found to prevent HSV-2 transmission in a mouse model, and three oligonucleotides (REP 2006, 2031 and 2107) reduced CMV liver titers upon intraperitoneal administration in a mouse model.

The specification teaches the in vitro inhibition of HSV-2 using oligonucleotides which are partially complementary to a target HSV-2 gene sequence. These experiments, however, are not representative of providing in vivo treatment or

prophylaxis, nor do they adequately represent the genus of sequences comprising oligonucleotides of at least 29 nucleotides in length with anti-viral activity occurring principally by a non-sequence complementary mode of action.

Applicant is correct that in vivo efficacy has been shown for the particularly described oligonucleotides, REP 2006, 2031 and 2107, regarding their ability to prevent or reduce HSV-2 or CMV infections in appropriate animal models as indicated in the declaration. The instant application therefore appears to be enabled for the ability to treat CMV upon systemic administration of REP 2006, 2031 and 2107, and for the ability to treat or prevent HSV-2 infection upon administration of REP 2006 and 2031.

The full scope of the claims, however, drawn to methods for the prevention and treatment of HSV-2 comprising administration of any oligonucleotide at least 29 nucleotides in length with anti-viral activity occurring principally by a non-sequence complementary mode of action, is not enabled. The ability to predict a particular randomer's ability to treat or prevent a viral infection in a subject is a highly unpredictable endeavor. The ability of three oligonucleotides to provide treatment effects of CMV and of two oligonucleotides to provide treatment or prophylactic effects for HSV-2 is not correlative or representative of the ability to predict the efficacy of any randomer of 29 bases or more to provide such effects in a subject. This requires experimentation beyond that provided in the instant specification.

For these reasons, the instant rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, James Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
12-12-06

J Zara TC1600

JANE ZARA, PH.D.
PRIMARY EXAMINER

Application No.: 10/661,097

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: Please Provide SeQ ID Nos for ALL oligonucleotides disclosed in Spec.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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